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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,952	01/17/2002	Patricia S. Walker	D-2933CIP	2757

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,952	WALKER; PATRICIA S.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,10,12,36-39 and 43-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,10,12,36-39 and 43-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-4, 10, 12, 36-39 and 43-45 are pending.

Applicant's amendment filed March 28, 2005 is acknowledged, and applicants' response has been fully considered. Claims 1, 36, 39 and 45 have been amended, and claims 6, 7, 9 and 40-42 have been cancelled. Therefore, claims 1-4, 10, 12, 36-39 and 43-45 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claim 39, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicant's amendment to the claim and applicant's response at page 6 in the amendment filed March 28, 2005.

Claim Rejections - 35 USC § 103

3. The previous rejection of claims 6, 7, 9 and 40-42, under 35 U.S.C. 103(a) as being unpatentable over Borodic (U. S. Patent 5,183,462) taken with Vadoud-Seyedi *et al.* (Dermatology 201, 179 (September 2000)), is withdrawn in view of applicant's cancellation of the claim in the amendment filed March 28, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 2, 10, 12, 36, 37 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic (U. S. Patent 5,183,462) taken with Vadoud-Seyedi *et al.* (Dermatology 201, 179 (September 2000)) and Slate *et al.* (U.S. 6,645,169, filed September 20, 2005).

Borodic discloses the injection of an appropriate dose of a botulinum toxin such as pharmaceutical grade botulinum toxin type A to interrupt nerve impulse transmission across the neuromuscular junction (column 4, lines 50-58) and to attenuate tone of muscles about the eyes and forehead can remove wrinkles and brow furrows, and a sublethal dose of the toxin was injected into muscle at the sites superior border of the forehead and at a point approximately 15 mms superior to the brow (column 3, line 67-column 4, line 6; column 5, lines 5-19; column 9, lines 42-66; claims 1, 10, 12, 36 and 43-45). However, Borodic does not disclose the use of a needleless syringe. Vadoud-Seyedi *et al.* disclose mouse botulinum toxin A in NaCl solution is injected into patients with plantar hyperhidrosis with a Dermojet (a needleless injection system; the whole document; claims 2 and 37); and Slate *et al.* teach there are three types of injections that may need to be performed by a needless injector: 1) shallow, intra-dermal injections, where the fluid medicament is infused into skin; 2) medium depth, subcutaneous injections where the fluid medicament is infused into fatty tissue beneath skin; and 3) deeper intra-musclular injections where the fluid medicament is delivered directly into muscle tissue, and depending on the type of injection that is desired and the general nature or condition of the patient's skin, the fluid pressure that is necessary to make an appropriate hole can vary from injection to injection (column 1, lines 41-52; column 3, lines 8-63). At the time of invention was made, it would have been obvious that one of ordinary skill in the art has been motivated to combine the three

references to treat wrinkles and brow furrows by administering botulinum toxin A to muscles associated with brow furrows as taught by Borodic using a needleless injector as taught by Vadoud-Seyedi *et al.*, and the injector can have a sufficient pressure to deliver the medicament to the muscle tissue (deeper intra-musclular injection) as taught by Slate *et al.* because Vadoud-Seyedi *et al.* indicate the pain injection with a Dermojet is acceptable, and there were neither paresthesias nor other side effects, and suggest the injection of botulinum toxin with a Dermojet is an effective and comfortable technique (page 179, third and last paragraph); and Slate *et al.* suggest the fluid pressure of injector can be varied depending on the type of injection to be made (i.e., intra-dermal, subcutaneous or intra-muscular). Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

5. Claims 3, 4, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic in view Vadoud-Seyedi *et al.* and Slate *et al.* as applied to claims 1, 2, 10, 12, 36, 37 and 43-45 above, further in view of McCabe *et al.* (U. S. Patent 5,525,510).

Borodic discloses the injection of an appropriate dose of a botulinum toxin such as pharmaceutical grade botulinum toxin type A to interrupt nerve impulse transmission across the neuromuscular junction (column 4, lines 50-58) and to attenuate tone of muscles about the eyes and forehead can remove wrinkles and brow furrows, and a sublethal dose of the toxin was injected into muscle at the sites superior border of the forehead and at a point approximately 15 mms superior to the brow (column 3, line 67-column 4, line 6; column 5, lines 5-19; column 9, lines 42-66; claims 1, 10, 12, 36 and 43-45); Vadoud-Seyedi *et al.* disclose mouse botulinum toxin A in NaCl solution is injected into patients with plantar hyperhidrosis with a Dermojet

(claims 2, 6, 37 and 40); Slate *et al.* suggest the fluid pressure of injector can be varied depending on the type of injection to be made (i.e., intra-dermal, subcutaneous or intra-muscular), and the combined references teach the treatment of wrinkles and brow furrows by administering botulinum toxin A into muscle with a Dermojet having sufficient pressure to deliver the medicament to muscle tissue. However, Borodic, Vadoud-Seyedi *et al.* and Slate *et al.* do not disclose the use of a botulinum toxin coated onto the carrier. McCabe *et al.* teach the biological material such as DNA, RNA, proteins or peptides is coated onto the carrier particles such as small gold beads or spheres (column 6, lines 22-35; claims 3, 4, 38 and 39). At the time of invention was made, it would have been obvious that one of ordinary skill in the art to combine the four references to treat wrinkles and brow furrows using the method taught by Borodic, Vadoud-Seyedi *et al.* and Slate *et al.* with botulinum toxin A coated onto the gold sphere taught by McCabe *et al.* because the treatment with neurotoxin coated onto the gold particle would be safer since the high density carrier with small particle size would readily enter living cells without injuring the cells. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

In response, applicant indicates the present claims recite the botulinum toxin is administered to a human subject using a needless syringe having a pressure sufficient to deliver the botulinum toxin to a muscle tissue associated with a wrinkle or brow furrow, while Vadoud-Seyedi *et al.* disclose needleless injection of a botulinum toxin into the sole of a pateint's foot to treat plantar hyperhydrosis, and plantar hyperhydrosis is a condition involving excessive secretions from plantar sweat glands. Sweat glands are located in the dermal layer of the skin (e.g., see Exhibit A in the amendment filed August 24, 2004) and are innervated by the

sympathetic nervous system, a subset of the autonomic nervous system. Vadoud does not disclose, teach, or even suggest the use of a botulinum toxln to treat wrinkles or brow furrows; Boridic discloses administration of a botulinum toxin by injection using a syringe with a needle, Borodic does not disclose, teach, or even suggest the use of a needleless syringe to deliver a botulinum toxin for any purpose, let alone to treat wrinkles and brow furrows; a person of ordinary skill in the art would not be motivated to combine Borodic and Vadoud, as proposed by the Examiner, because Vadoud only discloses the use of a botulinum toxin to interfere with the sympathetic nervous sysrem. In particular, Vadoud only discloses needleless administration of a botulinum toxin to interfere with a neuronal influence on a sweat gland located in the dermal layer of the skin, this actually teaches away from the claimed methods using a needleless injection of botullnum toxin to treat wrinkles or brow furrows by reducing a muscle contraction, where muscle tissue is located below the dermal layer; as the Examiner has acknowledged, treatment of wrinkles and brow furrows is different and distinct from treatment of other conditions; claims 3, 4, 38 and 39 are similarly unobvious from and patentable over the combination of Borodic in view Vadoud-Seyedi *et al.* and further in view of McCabe *et al.*; and each of the present dependent claims is separately patenable over the prior art because none of the prior art disclose, teach or suggest the additional features recited in the claims (pages 7-10 of the response).

The response has been considered, however, the argument is not found persuasive because Boridic discloses the treatment of a wrinkle or brow furrows by administering a botulinum toxin using a syringe with a needle into muscles (column 5, lines 5-19) at the sites superior border of the forehead and at a point approximately 15 mms superior to the brow

(column 9, lines 42-66), which meet the criteria of claim 45 regarding the adminstration site; and the secondary reference, Vadoud-Seyedi *et al.* teach a technique of injection using needleless syringe (e.g., a Dermojet), which has advantages as compared to injection with needle, e.g., the technique is safer and the injection with pain level is acceptable. McCabe *et al.* teach the biological material can be coated onto the carrier such as gold beads for needleless injection. Although Vadoud-Seyedi *et al.* teach using botulinum toxin to treat plantar hyperhidrosis, which is a different condition from wrinkle or brow furrows, the reference does disclose the advantages of using a Dermojet in the treatment. Furthermore, the advantage of using needleless injector (e.g., less pain, no risk of infection-safer) is well known in the art and has been stated in Bellhouse's patents (e.g., US. Patent 5,899,880, column 1, lines 61-65), which are incorporated in their entirety by reference in the specification (page 23, lines 17-26); and Slate *et al.* suggest the fluid pressure of injector can be varied depending on the type of injection to be made (i.e., intra-dermal, subcutaneous or intra-muscular). Therefore, the motivation for a person of ordinary skill in the art to combine the references to inject a botulinum toxin with a needleless syringe for treating wrinkles and brow furrows is the advantage of using needleless injector, which is safer and less pain when compared to injection with a needle as indicated in Vadoud-Seyedi *et al.*, and an appropriate pressure of the injector can be applied if intra-muscular injection is needed as indicated by Slate *et al.* Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

6. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CMK
May 30, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER